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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,256	12/15/2003	Sheng-Ping Zhong	12013/59103	5800
26646	7590	07/01/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/737,256	Applicant(s) ZHONG ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-43 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-43 and 47-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 36-43 and 47-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,682,771. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 36 of the instant application is merely a broader version of the patented claim 1, patented claim 1 incorporating the limitations of claims 36 and 51 of the instant case. Dependent claims of the instant case are also present as dependent claims of the patented case.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 51, which depends on claim 36, further limits a "second coating", however there is no "second coating" in claim 36.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 36-42, 47-50, and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (US 6,395,326 B1) in view of Tisone (6,063,339).

Castro et al. teach coating a medical device substrate comprising placing the substrate in a holder assembly (col. 8, line 29), placing a first agent into a first chamber connected to an inkjet printing head dispenser, delivering the first agent to the print head (col. 8, lines 57-60), and moving the dispenser relative to the medical device in the x, y, and z directions to force the first agent onto the medical substrate in a desired pattern (col. 16, line 12).

As outlined above, Castro teaches the use of an inkjet print head, but fails to teach that an inkjet print head would meet Applicant's limitation requiring a "solenoid fluid dispensing head".

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Tisone teaches a dispensing apparatus for dispensing desired patterns of reagent onto a medical substrate in the x, y, and z directions (abstract). Tisone teaches the use of solenoid valve dispensing heads, such as those commonly used in inkjet printing heads, in the method of his invention.

Since Castro teaches the use of an inkjet print head in coating a medical device in desired patterns and Tisone teaches the use of solenoid dispensing heads in coating a medical substrate in desired patterns and that it is well known that solenoid printheads are used in inkjet printheads, Tisone would have reasonably suggested the use of a solenoid type fluid dispensing head as the inkjet print head of Castro. It would have been obvious to one of ordinary skill in the art to use the solenoid type printhead of Tisone in Castro's method of using an inkjet printhead because Tisone teaches solenoid valve dispensers are commonly used for inkjet printing applications.

Regarding claim 37, Castro teaches the use of a second coating agent and the use of more than one applicator (col. 9, line 15; col. 19).

Regarding claims 38 and 47, it is Examiner's position that it would have been obvious to an ordinary artisan to select coating thicknesses of the therapeutic coatings to achieve a desired dose of therapy to a patient. An ordinary artisan would vary the dosage along the medical device to enhance therapy in more disease-prone regions of the device, once implanted. It is well settled that determination of optimum values of cause

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effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 39 requiring the agents to be masking materials, Examiner notes that the therapeutic agents of Castro would inherently cover, and thus mask, the underlying substrate.

Regarding claims 40 and 48, requiring that the therapeutic agents "communicate information about the medical appliance", Examiner notes that Castro teaches a wide variety of agents (col. 14), some of which would communicate some information about the device. For example, Taxol communicates toxicity to surrounding cells.

Regarding claims 41 and 49, Castro teaches the use of non-thrombogenic agents (col. 13, line 65).

Regarding claim 42, Castro teaches a number of embodiments, such as for coating a second composition to overlay a first composition in the same pattern (col. 19). Castro does not specifically teach that the two solenoid dispenser heads of claim 37 are "in fluid communication with a common nozzle", however, it is Examiner's position that it would have been obvious to an ordinary artisan coating two different overlaying coatings to share the nozzle that is programmed to travel in a predetermined pattern so that the same nozzle can be used to deliver the first, followed by the second, coating

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layers. When two valves share a common nozzle, the second coating operation can commence without changing nozzles from the first coating layer.

Regarding claims 52-53, Castro teaches the use of therapeutic agents as printed coatings, as outlined above.

Castro teaches rotating the dispensing head around the medical device, as required by claim 54 (col. 4, line 56). Regarding claim 55, Examiner notes that motion is relative. Moving the medical device around the dispensing head is equivalent to moving the dispensing head around the medical device.

5. Claims 43 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro in view of Tisone, as applied to claims 36-42, 47-50, and 52-55 above, and further in view of Hossainy et al. (6,287,628 B1).

Castro teaches a wide and non-limiting variety of therapeutic agents to be printed onto his stent device including anti-thrombotics, antiproliferatives, Taxol, and inhibitors, among others.

Hossainy teaches the use of anti-thrombotics, antiproliferatives, Taxol, radioactive agents, and radiopaque agents on stents.

Since Castro teaches the use of therapeutics on his stents and Hossainy teaches the use of therapeutics such as radiopaque agents on his stents, Hossainy would have reasonably suggested the use of radiopaque agents on the stents of Castro. It would

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have been obvious to one of ordinary skill in the art to use the teachings of Hossainy in the method of Castro in view of Tisone to provide radiopacity to the stent of Castro to enable a surgeon to locate an implantable stent upon X-ray.

Conclusion

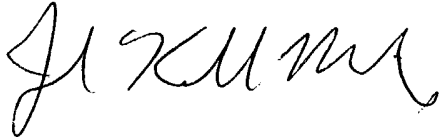
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wu (WO 01/91918) is cited for teaching the use of an inkjet printhead for applying coatings to medical devices, similar to Castro, above. Martin, Jr. et al. is cited for teaching the use of solenoid valve nozzles for coating medical appliances, similar to Tisone, above.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "JKM", with a stylized flourish at the end.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
June 27, 2004